

Material Safety Data Sheet

Version: 1.0
Creation Date: May 12, 2021
Revision Date: May 12, 2023

Part I Chemical and Enterprise Identification

Product Chinese Name: 钆特酸葡胺

Product English Name: Gadolinium DOTA Meglumine

Product Trade Name: Gadoterate Meglumine

Enterprise Chinese Name: 杭州凯莫思生化有限公司

Enterprise English Name: Kaimosi BioChem Tech Co.,Ltd

Tel: +(86) 571 8719 1913

Fax: +(86) 571 8756 2572

Recommended and restricted use:

For disease diagnosis. It is used for MRI examination of brain and spinal cord diseases, spinal diseases and othersystematic pathological examinations (including angiography).

Part II Hazards Description

Emergency Overview:

Severe eye irritation. May lead to respiratory tract irritation.

GHS Hazard Category:

Severe eye injury/eye irritation category 2

Specific target organ toxicity—Single exposure category

GHS labeling elements, including precautions



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Hazard statement:

H319 Cause severe eye irritation

H335 May cause respiratory tract irritation

Precaution Statements (Precautions):

P264 Complete cleaning after operation.

P280 Wear protective gloves/protective clothing/goggles/masks.

P261 Avoid inhaling dust / smoke / gas / fog / vapor / spray.

P271 Used outdoors or at well-ventilated place.

Precaution Statements (Accident Response):

P305+P351+P338 In case of eye exposure: Flush carefully with water for several minutes. If you wear contact lenses and can be easily taken out, then take out the lens and continue flushing.

P337+P313 If eye irritation persists: Seek medical advice/treatment.

P304+P340 If inhaled by mistake: Transfer the person to well-ventilated place and keep a comfortable position for breathing.

P312 If feeling unwell, call the detoxification center/doctor

Precaution Statements (Safety Storage):

P403+P233 Store in well-ventilated place and keep the container closed.

P405 The chemical must be stored with lock.

Precaution Statements (Waste Disposal):

P501 Dispose the contents/containers according to local regulations.

Healthy Effects:

Cause skin irritation, severe eye irritation and respiratory tract irritation.

Part III Composition/Information on Ingredients

Chemical Properties:

Pure Matter

Composition:

(Chemical Name) Hazardous component	CAS No.	Concentration or concentration range%
钆特酸葡胺 Gadoterate Meglumine	92943-93-6	100%

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Part IV First Aid Measures

General Information:

Call your doctor if symptoms persist.

Inhalation:

Move to fresh air immediately.

Skin Contact:

Take off the contaminated clothes and flush the skin thoroughly with soap and water. Seek medical help if feeling unwell.

Eye Contact:

Separate the eyelids and wash them with flowing clean water or normal saline. Seek medical treatment immediately.

Ingestion:

Rinse mouth with water and do not induce vomiting. Seek medical treatment immediately.

Advice to Rescuer:

Transfer the patient to a safe place. Consult a physician. Show this Material Safety Data Sheet to the doctor at the scene.

Notes to Physician:

Data absence

Part V Fire Fighting Measures

Firefighting Methods and Extinguishing Agents (suitable and unsuitable):

Suitable extinguishing media: Use water spray, dry chemical, foam or carbon dioxide extinguishing media

Unsuitable extinguishing media: Avoid using water to extinguish the fire, or else it may cause splashing of flammable liquid and spread the fire.

Special hazards (e.g., hazardous products after combustion):

No data.

Firefighting precautions and protective measures:

Firefighters must wear air breathing apparatus and fire-fighting clothes to extinguish the fire in the direction of the wind. Move containers from the fire site to an open place as much as possible. If the container in the fire site has changed color or made a noise from the safety relief device, the personnel must be evacuated immediately.

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Isolate the accident site and prohibit irrelevant personnel from entering. Collect and dispose firefighting water to prevent environmental pollution

Part VI Leakage Emergency Measures

Protective measures and equipment for working personnel (emergency and non-emergency personnel)

It is recommended that emergency treatment personnel wear air breathing apparatus, anti-static clothing and rubber oil resistant gloves.

Emergency procedure:

Do not touch or cross spills. All equipment used in operation should be grounded. Cut off the leak source as much as possible. Eliminate all ignition sources. Define alert areas based on areas affected by liquid flow, vapor or dust diffusion, evacuation of irrelevant personnel from side air, upwind direction to safety areas.

Environment Protection Measures:

Collect spills to avoid environmental contamination. Prevent leakage into sewers, surface waters and groundwater.

Containment and removal methods for leaking chemicals and disposal materials used (small leaks, large leaks):

Small leaks: Leaking fluids were collected in airtight containers whenever possible. Absorb with sand, activated carbon or other inert material and transfer to a safe place. Do not flush into sewer.

Large leaks: Construct a dike or pit for the collection of leaks. Seal off the drain. Cover with foam to inhibit evaporation. Transfer to a tanker or special collector with explosion-proof pump for recycling or transport to waste disposal.

Precautions against secondary hazards:

None

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Part VII Handling and Storage

Precautions for safe operation (technique, ventilation, contact):

Operators are specially trained and strictly follow operating procedures. Operations should be handled in a location with local or full ventilation facilities. Avoid contact between eyes and skin and avoid breathing vapors. See Part VIII for personal protection measures. Keep away from fires and heat sources and do not smoke in the workplace. Use explosion-proof ventilation systems and equipment. If filling is required, the flow rate should be controlled and grounding devices should be provided to prevent static build-up. Avoid contact with prohibitions such as oxidants (see Part X for Incompatible substances). Handle with light to prevent packaging and container damage. Empty containers may retain hazardous material. Wash hands after use and avoid eating or drinking at the workplace. Be equipped with corresponding fire-fighting equipment and emergency treatment equipment for leakage.

Precautions for safe storage (technique, incompatibility, packaging):

Store in a cool and ventilated warehouse. The storage temperature shall not exceed 37 °C. It should be stored separately from oxidants and edible chemicals and should not be mixed (refer to Part X for Incompatible substances). Keep container tightly closed. Keep away from ignition and heat sources. Lightning protection equipment must be installed in the warehouse. The exhaust system shall be provided with grounding device for guiding electrostatic discharge. Use explosion-proof lighting, ventilation settings. Equipment and tools liable to sparks must not be used. The storage area should be equipped with emergency leak handling equipment and suitable containment materials.

Part VIII Exposure Control and Personal Protection

Occupational Exposure Limits:

Component	CAS No	MAC Maximum Allowable Concentration	PC-TWA Permissible Concentration- Time Weighted Average	PC-STEL Permissible Concentration- Short Term Exposure Limit	Baseline
Gadoterate Meglumine	92943-93-6	NO DATA	NO DATA	NO DATA	NO DATA

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Biological Limit

Component	CAS No	Biological monitoring indicators	Biological Limits	Sampling Time	Baseline
Gadoterate Meglumine		NO DATA	NO DATA	NO DATA	NO DATA

Monitoring Method:

GBZ/T 160.1 ~ GBZ/T 160.81-2004 Workplace Air - Determination of toxic substances (series of standards), EN 14042 Workplace Air - Guidance on procedures used to assess exposure to chemical or biological agents

Engineering Control Method:

It is recommended to separate the workplace from other workplaces. Closed operation to prevent leakage and strengthen ventilation. Automatic alarm devices and emergency ventilation facilities shall be set. Emergency evacuation channels and necessary danger elimination areas shall be set up. Set up red area warning lines, warning signs and warning instructions in Chinese, and set up the communication alarm system. Provide safety shower and eyewash equipment.

Personal Protection Equipment:

Respiratory Protection:

When airborne concentrations are out of specification, wear a filtered gas mask (half mask). Air-carrying breathing apparatus should be worn in emergency situations or evacuation.

Hand Protection:

Wear rubber oil-resistant gloves.

Eye/Face Protection:

Wear chemical safety glasses.

Skin and Body Protection:

Wear anti-poison penetration clothing.

Other Protections

None

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Part IX Physic-Chemical Properties

Appearance and Characteristics (State of matter, appearance and color):

State of matter: Solid

Appearance: White or off-white powder

Color: White

Odor:

No data

Odor Threshold:

No data

pH value (Concentration):

No data

Melting/Freezing Point:

No data

Boiling point, initial boiling point and boiling range:

No data

Flash Point:

No data

Evaporation rate:

No data

Flammability (solid, gas):

No data

Explosion limit (upper and lower limit):

No data

Vapor Pressure:

No data

Vapor Density:

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No data

Density/Relative Density (1 for water):

No data

Solubility:

No data

Cn-octanol/water partition coefficient:

No data

Critical Temperature (°C) :

No data

Critical Pressure (MPa) :

No data

Auto-ignition Temperature (°C) :

No data

Decomposition Temperature (°C) :

No data

Combustion Heat (KJ/mol) :

No data

Viscosity:

No data

Part X Stability and Reactivity

Reactivity:

No data

Chemical Stability:

The product is stable when stored and used at normal ambient temperature.

Possibility of hazardous reactions:

No data

Conditions to Avoid:

Electrostatic discharge, heat, humidity, etc.

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Contraindicated Substances:

No data

Hazardous Decomposition Products:

No data

Part XI Toxicological Information

Acute Toxicity:

Median lethal dose (LD50) orally - rat No data

Median lethal dose (LD50) inhalation - rat No data

Skin irritation or corrosion:

No data

Eye irritation or corrosion:

No data

Respiratory or skin sensitization::

No data

Germ cell mutagenicity:

No data

Carcinogenicity:

This product has no known carcinogenic chemicals.

Reproductive Toxicity:

No data

Specific target organ system toxicity (single exposure):

No data

Specific target organ system toxicity (repeated exposure):

No data

Inhalation Hazard:

No data

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Potential health hazards (inhalation, ingestion, skin contact, eye contact)

No data

Part XII Ecological Information

Ecotoxicity (fish, other):

Toxicity on fish:

Median lethal concentration (LC50) - fish, 96h No data

Toxicity on Daphnia and other aquatic invertebrates:

Median Lethal Concentration (LC50) - Daphnia, 48h No data

Toxicity on algae:

Half maximal effect concentration (EC50) - algae No data

Persistence and Degradability:

No data

Potential bio-accumulation:

No data

Mobility in soil:

No data

Other adverse effects:

No data

Part XIII Disposal Considerations

Waste Chemicals:

Recycle as much as possible. If recycling is not possible, dispose of by incineration. Do not discard product by draining into sewer

Contaminated packaging::

Return containers to the manufacturer or dispose of in accordance with national and local regulations.

Waste Precautions:

Refer to national and local regulations before disposal.

Safety precautions for disposal personnel are described in Part VIII.

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Part XIV Transportation Information

UN dangerous goods number (UN no.):

No data

UN Shipping Name:

No data

UN Hazard Classification:

No data

Packaging Category:

No data

Marine pollutant (yes/no):

No

Packaging Marking:

No data

Packaging Method:

Pack according to manufacturer's recommended method.

Shipping Precautions:

The transportation vehicles shall be equipped with corresponding fire-fighting equipment and emergency treatment equipment for leakage. Do not mix with oxidizers, edible chemicals, etc. Vehicle exhaust pipes used to ship this item must be equipped with a flame retardant. The tank (tank) vehicle shall be provided with grounding chain during transportation, and hole diaphragm may be set in the tank to reduce the static electricity generated by oscillation. Do not use mechanical equipment and tools liable to spark.

In summer, it is recommended to be transported in the morning and evening. During transportation, it is necessary to prevent exposure to sunlight, rain and high temperature. Keep away from fire, heat source and high temperature area during stopover. Road transport shall follow the prescribed route and shall not stop in residential areas or densely populated areas. Slips are forbidden during rail transport. It is forbidden to use wooden boats or cement boats for bulk transportation. Hazard signs and notices shall be posted on the means of transport according to relevant transportation requirements.

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Part XV Regulatory Information

Regulations:

Globally Harmonized System of Classification and Labeling of Chemicals-Revised 4 ST/SG/AC.10/30/Rev.4
Guidance on the Compilation of Safety Data Sheet for Chemical Products

GBT 16483 Safety Data Sheet for Chemical Products Content and Order of Sections

Regulations on the Safety Management of Hazardous Chemicals (2011, Order No. 591)

Safe Use of Chemicals in the Workplace ([1996] Labor No. 423)

Safety Specifications for Chemical Classification, Warning Labels and Precautionary Statements

Common Chemical Hazardous Classification and Marking

Dangerous Goods List (GB12268) ;

Hazardous Chemicals List (Edition 2015) ;

Dangerous Goods Classification and Product Name Number (GB6944) ;

General Guidelines for Classification and Hazard Disclosure of Chemicals

General Rules for Storage of Common Chemical Hazardous Substances

Occupational Exposure Limits for Hazardous Agents in Public Places Part 1: Chemical Hazardous Agents

Occupational Exposure Limits for Hazardous Agents in Public Places Part 2: Physical Factors

All users must enable and comply with this chemical safety data sheet (SDS) and the State Administration of Work Safety (SAWS), Ministry of Environmental Protection (MEP), Ministry of Health (MOH), Ministry of Human Resources and Social Security (MHR&SS) of the People's Republic of China) and other regulations issued by the Ministry of Worker protection measures and environmental emission control methods.

HSE management regulations for this product:

Law of the People's Republic of China on the Prevention and Treatment of Occupational Diseases (Chairman's Decree No. 60 of 2001)

Labor Protection Articles Selection Rules

Classification Catalog of Hazardous Factors of Occupational Diseases ([2002] No. 63);

This product is not listed in China's Hazardous Chemicals List (2015 Edition), Hazardous Goods List (GB12268-2005), Catalogue of Highly Toxic Articles (2003 Edition), Catalogue of Highly Toxic Chemicals (2002 Edition), Catalogue of Precursor Chemicals (Order No. 445 of the State Council in 2005), Catalogue of Toxic Chemicals Strictly Restricted in Import and Export in China and Catalogue of Prohibited Import Goods.

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Part XVI Other Information

References:

<https://echa.europa.eu/information-on-chemicals>

Revision Date:

This edition (00th) is prepared according to GB/T 16483-2008, GB/T 17519-2013 and GB 30000 series classification standards

Revision Description:

This manual is used for general industrial purposes, and the information provided is to ensure that the product is properly used and disposed of, and is not a warranty of the manufacturer. Currently, it is made based on reliable reference data and test data. Provide reference for those who need it, please make appropriate countermeasures based on this information according to their respective responsibilities and actual situation.

This sheet documents the product safety information. For the necessary conditions for quality assurance, please refer to the technical materials, specifications, etc.

For more information, please contact Kaimosi BioChem Tech Co.,Ltd.

Abbreviations:

GHS: Globally Harmonized System of Classification and Labeling of Chemicals

CAS No.: Chemical Abstracts Service

MAC (maximum allowable concentration): Refers to the concentration of toxic chemicals that should not exceed in the workplace, within a working day, at any time.

PC-TWA: Permissible concentration-Time Weighted Average: Refers to the average allowable contact concentration of 8h working day and 40h working week with time as weight.

PC-STEL: Permissible concentration-Short Term Exposure Limit: Refers to the concentration at which short time (15 min) exposure is allowed under the premise of complying with PC-TWA.

ACGIH: American Conference of Governmental Industrial Hygienists

GBZ/T: Recommended national occupational health standard code

WS/T: Recommended criteria by health organization

PPE: Personal Protective Equipment

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UN No.: The number assigned to dangerous goods in the United Nations Recommendation on the Transport of Dangerous Goods

ICAO: International Civil Aviation Organization: International Air Dangerous Goods Code

IMDG: International Marine Dangerous Goods Code

ADR: Authorisation Dangerous Road

RID: Regulations Concerning the International Carriage of Dangerous Goods

AND: European Agreement concerning the International Carriage of Dangerous Goods by Road

Disclaimer:

All relevant information is provided in this SDS comprehensively and truly, but we do not guarantee the breadth and accuracy of its decisions. This SDS provides safety precautionary information for the product only to those persons who have received appropriate professional training and use the product. Personnel obtaining the SDS must make independent judgments about the suitability of the SDS under special conditions of use. Under special conditions of use, the Company shall not be liable for any damage caused by the use of this SDS.